K022067

SEP 11 2002

510(k) Summary

Category:	Comments
Sponsor:	Boston Scientific Corporation/EP Technologies, Inc. 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Andrea L. Ruth, RAC Senior Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: 408.895.3625 Fax: 408.895.2202 Email: rutha@bsci.com
Device Common Name	Cardiac Introducer Sheath
Device Proprietary Name	Convoy™ Advanced Delivery Sheath Kit
Device Classification Name	Introducer, Catheter
Device Classification	Class II, DYB
Predicate Device	Daig Corporation, Fast-Cath Introducing Sheath
Predicate Device Manufacturer(s)	Daig Corporation, A Division of St. Jude Medical
Predicate Device Classification Name(s)	Introducer, Catheter
Predicate Device Classification(s)	Class II, DYB

Date Summary Was Prepared: June 14, 2002.

Description of the Device:

The Convoy Advanced Delivery Sheath Kit consists of: (1) a disposable Introducer Sheath, (2) a Vessel Dilator and (3) Guidewire with Guidewire Introducer. These devices are designed for the introduction of various types of cardiovascular catheters to the heart.

The Introducer Sheaths are constructed in a range of curve reach configurations, diameters and lengths to respond to physician preferences. The Introducer Sheath configurations covered under the subject 510(k) Premarket Notification include 8.5 F

and 9.5 F diameter, angles ranging from 0° - 180°, radius of curvatures ranging from 0.6" - 1.75", lengths of 60 cm - 101.5 cm, and may be configured with either one, two or three curves in a single or dual plane.

Intended Use:

The Convoy Advanced Delivery Sheath Kit is intended to facilitate the intracardiac placement of interventional devices.

Comparison to Predicate Devices:

	Predicate Device	Modified Device
510(k) Reference	K964518	Current Submission
Intended Use	Intracardiac Placement of Interventional Devices	Same
Device Description	Intracardiac Introducing Sheath	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	Daig Corp	EPT/BSC
Device Classification	Class II, DYB; 21 CFR §870.1340	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Boston Scientific Corporation/ EP Technologies, Inc.
Ms. Andrea L. Ruth
Senior Associate, Regulatory Affairs
2710 Orchard Parkway
San Jose, CA 95134

Re: K022067
Convoy Advanced Delivery Sheath Kit
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II
Product Code: DBY
Dated: June 24, 2002
Received: June 25, 2002

Dear Ms. Ruth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K022067

Device Name: Convoy™ Advanced Delivery Sheath Kit

Indication for Use:

The Convoy Advanced Delivery Sheath Kit is intended to facilitate the intracardiac placement of interventional devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022067

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)